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| 09/582,152 | 09/05/2000 | Christopher Raymond Jones | 00456/HG | 6861 |

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EXAMINER

HUI, SAN MING R

| ART UNIT | PAPER NUMBER |
|----------|--------------|
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1617

DATE MAILED: 04/09/2003

18

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Applicant(s)

09/582,152

Applicant(s)

JONES ET AL.

Examiner

San-ming Hui

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 08 January 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☐ Claim(s) _____ is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☐ Claim(s) _____ is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on January 8, 2003 has been entered.

Applicant's amendments filed January 8, 2003 have been entered.

Claims 1, 3-5, 9, 12-16, and 18-21 are pending.

Warning

Applicant is advised that should claim 16 be found allowable, claim 18 will be objected to under 37 CFR 1.75 as being a substantial duplicate thereof. When two claims in an application are duplicates or else are so close in content that they both cover the same thing, despite a slight difference in wording, it is proper after allowing one claim to object to the other as being a substantial duplicate of the allowed claim. See MPEP § 706.03(k). Both claims are drawn to the same method of applying the same composition in order to prevent, inhibit, or remove microbial contamination in aqueous systems.

Claim Rejections - 35 USC § 112

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The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1, 3-5, 9, 12-16, and 18-21 are rejected under 35 U.S.C. 112, first paragraph, because the specification does not reasonably provide enablement for any non-surfactant biopenetrant. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with these claims.

There is no adequate direction provided by the applicant as to how to select a suitable biopenetrants to be used in the invention to form a synergistic anti-microbial composition and remove microbes in aqueous system. Furthermore, the instant specification does not provide any working examples to show how non-surfactant biopenetrants may be used successfully in the invention to form a synergistic anti-microbial composition and remove microbes in aqueous system.

Moreover, it is known in the art that different compounds may have different potency and activity because of the structural and conformational differences in the compounds. Therefore a different biopenetrants may be reasonably expected to yield a different result in a synergistic anti-microbial composition or in a method of inhibit microbes in aqueous system. Due to this unpredictability, it would prevent the skilled artisan from determining compounds which may be termed an "biopenetrant" to retain the desired function of the instant invention to form a synergistic anti-microbial composition and remove microbes in aqueous system without undue experimentation.

Please note that claims 1, 13, and 18 recite a limitation “synergistic” and “non-surfactant biopenetrant synergist” in line 1 and line 3 respectively. Synergism is an unexpected and highly unpredictable effect. Applicant must demonstrate such an unexpected result for a representative number of compounds of the very broad genus herein (See MPEP 716.02(b)). Synergism should be demonstrated with evidence that the differences in results are in fact unexpected and unobvious and of both statistical and practical significance. *Ex parte Gelles*, 22 USPQ2d 1318, 1319 (Bd. Pat. App. & Inter. 1992). Moreover, evidence as to synergism (i.e., unexpected benefits) must be “clear and convincing” *In re Lohr*, 137 USPQ 548 (CCPA 1963), and be of a scope reasonably commensurate with the scope of the subject matter claimed, *In re Linder*, 173 USPQ 356 (CCPA 1972). In the instant case, such evidence to demonstrate synergism is not present.

Response to arguments regarding rejections under 35 USC 112, first paragraph

Applicant's remarks filed January 8, 2003 regarding the specific biopenetrants are recited in the claims have been considered, but are not found persuasive. The claims are drawn to a synergistic combination of THP and a biopenetrant, which can be a polymer or copolymer having certain functional groups such as quaternary ammonium groups. The issue at hand is that no synergism was demonstrated. With a wide range of polymers and copolymers claimed as biopenetrants, one of skilled in the art would have to perform undue experimentation in order to ascertain the suitable biopenetrants that possesses synergistic effect when combine with THP. Evidence of a greater than

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expected result may also be shown by demonstrating an effect which is greater than the sum of each of the effects taken separately (See MPEP 716.02(a)). Furthermore, the unexpected results should be demonstrated with evidence that the differences in results are in fact unexpected and unobvious and of both statistical and practical significance.

Ex parte Gelles, 22 USPQ2d 1318, 1319 (Bd. Pat. App. & Inter. 1992). Moreover, evidence as to any unexpected benefits must be "clear and convincing" *In re Lohr*, 137 USPQ 548 (CCPA 1963), and be of a scope reasonably commensurate with the scope of the subject matter claimed, *In re Linder*, 173 USPQ 356 (CCPA 1972). In the instant case, example 1 merely compares the combination of the instant claimed composition against other commercial combination products. It is not clear whether those products are the closest standard for the comparison of antimicrobial activities. The explanation in page 6 of the declaration filed January 8, 2003 does not clarify the above concerns. The cited prior art clearly teaches the herein claimed components are known to be useful as antimicrobial individually. It flows logically to combine both agents in a single composition and method useful for the very same purpose (See *In re Kerkhoven* 205 USPQ 1069). At least additive effect would be expected. In the instant case, no clear and convincing results are seen to be present over the cited prior art. Please note that the cited prior art does not require an anionic surfactant in order for the composition to be useful. Therefore, the comparison in example 1 is not considered as unexpected results over the cited prior art.

Claims 1, 3-5, 9, 12-16, and 18-21 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. The instant invention is drawn to a method of treating aqueous systems to prevent microbial contamination. Please note that in order to prevent contamination or keep contamination from happening, one will have to inhibit the contact of the microbes with the aqueous system. Such inhibition cannot be achieved chemically. Once the contact between the microbe and the aqueous systems is made, the systems become contaminated. The instant claims do not recite any steps drawn to physical inhibition of the microbes from entering or mixing into the aqueous systems. The instant specification does not provide and information or disclosure that such inhibition can be done. Therefore, the specification does not enable one of skilled artisan to practice the herein claimed invention.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 18-21 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The expression “ together, or separately, the biocidally synergistic mixture” in claim 18 renders the claims indefinite as to what other materials would be added with

the biocidal mixture. Please note that together usually means at least two or more items. The instant claims only recite one mixture.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1, 3-5, 9, 12-16, and 18-21 are rejected under 35 U.S.C. 103(a) as being unpatentable over Davis et al. (GB 2 145 708) in view of Legros (WO91/04668 from the Information Disclosure Statement received June 21, 2000), Gerhold (WO96/14092), Bardoliwalla et al. (US Patent 4,599,372), West et al. (US Patent 4,602,011), and Davis et al. (EP 0491 391), references of record.

Davis '708 teaches an antimicrobial composition comprising THP and a dispersants, which are reasonably expected to enhance penetration of the active into organisms since enhanced dispersion of active agent throughout an area of water is expected to increase the number of water infecting organisms treated or contacted by the active at the same time. Davis'708 teaches that both agents can be employed in the treatment of water to control the growth of microorganisms (See particularly page 1, line 5-14 and 63-65; and page 2, lines 21-25). Davis '708 also teaches the concentration of THP is 10-30 ppm (See particularly page 2, 3-10). Davis'708 also teaches the condensate of THP with urea may be used in the composition and method

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(See particularly claim 7). Davis '708 teaches that THP is known to be used in a method of water treatment with a dispersant (See page 2, line 21-25).

Davis '708 does not expressly teach the use of a quaternary ammonium compound in the water treatment composition and method. Davis '708 does not expressly teach the use of poly[oxyethylene(dimethyliminio)ethylene(dimethyliminio)ethylene dichloride] in the water treatment composition and method. Davis '708 does not expressly teach the use of an alkyl benzene sulphonate having less than 5 aliphatic carbon atoms in the water treatment composition and method. Davis '708 does not expressly teach the use of glycol ether in the water treatment composition and method. Davis '708 does not expressly teach the use of phosphono polycarboxylic acid in the water treatment composition and method. Davis '708 does not expressly teach the use of 10 to 75% of THP and 0.1 to 10% of biopenetrant in the water treatment composition and method. Davis '708 does not expressly teach the use of surfactant in the water treatment composition and method.

Legros teaches the use of a quaternary ammonium compound in the water disinfecting composition and method (See particularly abstract; also page 3, line 1 – page 4, line 34; compound of formula I).

Gerhold teaches a biocidal composition and method employing poly[oxyethylene(dimethyliminio)ethylene(dimethyliminio)ethylene dichloride] as one of the active agent (See particularly page 5, line 14-16). In addition, Gerhold teaches that the biocidal composition and method may be used with surfactant (See particularly page 8, line 34-

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page 9, line 33). Moreover, Gerhold teaches that alkyl benzene sulphonate may be useful in forming the biocidal composition and method (See particularly page 9, line 13).

Bardoliwalla et al. teaches that methyl carbitol is useful in the waste water treatment composition (See particularly col.1, line 8-12 and also col.6, line 15-20; and claim 2).

West et al. teaches the employment of alkyl benzene sulphonate with a carbon side chain of two to 20 carbon atoms in an antimicrobial composition (See col.1, line 18-25; also col.4, line 15-18).

Davis '391 teaches that a phosphono polycarboxylic acid, 2-phosphono-1,2,4-tricarboxylbutane, may be used as a water treatment agent (See particularly page 2, line 16; and also page 4, line 28-36). Davis '391 also teaches the effective concentration of 2-phosphono-1,2,4-tricarboxylbutane should be 0.5 to 96% (See page 5, line 51-54).

It would have been obvious for one of ordinary skill in the art at the time the invention was made to incorporate any of the agents herein into an antimicrobial water treatment composition and method with 10 to 75% of THP and 0.1 to 10% of biopenetrant.

One of ordinary skill in the art would have been motivated to incorporate any of the agents herein to form a antimicrobial water treatment composition and method with 10 to 75% of THP and 0.1 to 10% of biopenetrant because combining the agents herein which are known to be useful to antimicrobial, water treating methods individually into a single composition and method useful for the very same purpose is prima facie obvious.

See *In re Kerkhoven* 205 USPQ 1069. Furthermore, the optimization of result effect parameters (dosage range, dosing regimens) is obvious as being within the skill of the artisan, absent evidence to the contrary.

It is applicant's burden to demonstrate unexpected results over the prior art. See MPEP 716.02, also 716.02 (a) - (g). Furthermore, the unexpected results should be demonstrated with evidence that the differences in results are in fact unexpected and unobvious and of both statistical and practical significance. *Ex parte Gelles*, 22 USPQ2d 1318, 1319 (Bd. Pat. App. & Inter. 1992). Moreover, evidence as to any unexpected benefits must be "clear and convincing" *In re Lohr*, 137 USPQ 548 (CCPA 1963), and be of a scope reasonably commensurate with the scope of the subject matter claimed, *In re Linder*, 173 USPQ 356 (CCPA 1972). In the instant case, examples 1-6 in the specification at page 17-22 have been considered but are not found persuasive as to the nonobviousness of the claimed composition and method invention for the treatment of aquatic systems to inhibit and prevent microbial growth. The data presented in example 1 has been considered but is not found persuasive as to unexpected results because data in example 1 merely compares the combination of the instant claimed composition against other commercial combination products. It is not clear whether those products are the closest standard for the comparison of antimicrobial activities. Further, the precise formulation of the composition products, i.e., in the anionic surfactant employed, is not disclosed. Therefore, no clear and convincing results are seen to be present over the cited prior art. The data of example 1 has been considered but is not found persuasive because data in example 1 merely compares the

combination of the instant claimed composition against a control. The effectiveness of the THP composition in example 3 is seen to be an expected effect based on the cited prior art. No synergistic effect is seen to be present. The data of examples 2, 4, and 6 merely demonstrate the effectiveness of the water treatment composition containing THP and an additional agent to inhibit or eradicate the bacteria in the water treatment method. This is seen to be an expected result based on the cited prior art. No comparison data to the closest prior art is presented in examples 2, 4, and 6. Therefore, no clear and convincing unexpected result is seen herein. The data of example 5 merely demonstrates the efficacy of different biopenetrants combined with THP in the water treatment method herein. The results have been considered and are seen to show an expected water-treatment effect based on the cited prior art. No clear and convincing unexpected results over the cited prior art is seen herein.

Response to Arguments regarding rejections under 35 USC 103

Applicant's rebuttal arguments filed January 8, 2003 averring synergism was demonstrated in the instant case have been considered, but are not found persuasive. Please see discussion above and the discussion below addressing the declaration by Mr. Jones filed January 8, 2003.

Applicant's rebuttal arguments filed January 8, 2003 averring that the cited prior art's teaching only a combination of THP and the thiocyanate biocides, with no biopenetrant present have been considered, but are not found persuasive. THP is known to used in a method of water treatment with a dispersant (See Davis'708 page 2,

line 21-25). Dispersions are reasonably expected to enhance penetration of the active into organisms since enhanced dispersion of active agent throughout an area of water is expected to increase the number of water infecting organisms treated or contacted by the active at the same time. Therefore, the teaching of Davis'708 is seen to suggest the combination of THP with a biopenetrant agent.

Response to the declaration by Mr. Jones filed January 8, 2003

Applicant's remarks with regard to the data in example 1 have been considered, but are not found persuasive as to the presence of unexpected results. Please see the discussion in both the responses to argument regarding rejection under 35 USC 112 and 103 above.

Applicant's arguments averring the cited prior art's failure to teach the employment of a non-foam forming surfactant have been considered, but are not found persuasive. Please note that arguments drawn to unclaimed limitations are considered moot.

Applicant's remarks with regard to the data in example 2 have been considered but are not found persuasive as to the presence of unexpected results. The results are not clear. For example, using 150ppm of 50% THPS/0.7% WSCP results in total kill after 45 hours; and there are still bacteria surviving in the 72 hours biofilm. It is not clear what the bacterial killing effectiveness of WSCP alone and that of THPS alone. Without knowing such information, one of ordinary skill in the art cannot evaluate whether the bacterial killing effects of the combination are merely additive or indeed

synergistic. Even if the data does show synergistic effect, the scope of the claims is not commensurate with the scope of showing.

Applicant's remarks with regard to the last experimental data in page 8 of the declaration filed January 8, 2003 have been considered, but are not found persuasive. It is not clear what the bacterial killing effectiveness of THPS alone and that of sodium lauryl sulphate alone. Without knowing such information, one of ordinary skill in the art cannot evaluate whether the bacterial killing effects of the combination are merely additive or indeed synergistic. Even if the data does show synergistic effect, the scope of the claims is not commensurate with the scope of showing.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to San-ming Hui whose telephone number is (703) 305-1002. The examiner can normally be reached on Mon 9:00 to 1:00, Tu - Fri from 9:00 to 6:00.


If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreeni Padmanabhan, PhD., can be reached on (703) 305-1877. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 308-4556 for regular communications and (703) 308-4556 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1235.

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San-ming Hui
April 2, 2003


SREENI PADMANABHAN
PRIMARY EXAMINER
4/4/03